

Barry J. Brett, Esq.
TROUTMAN SANDERS LLP
The Chrysler Building
405 Lexington Avenue
New York, New York 10174
(212) 704-6000

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Judge Hellerstein

-----X
DR. ANTHONY CERAMI,

07 CIV 5634

Plaintiff,

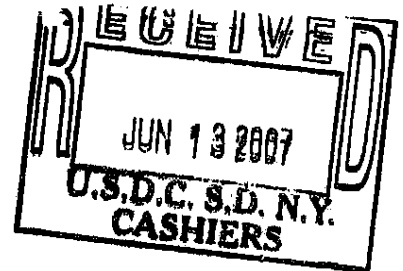
: COMPLAINT

- against -

: Jury Trial Demanded

NOVARTIS AG and
NOVARTIS VACCINES AND DIAGNOSTICS,
INC.,

Defendants.



-----X
Plaintiff, Anthony Cerami, by his undersigned attorneys, Troutman Sanders LLP, brings this civil action against the defendants named herein and alleges as follows:

NATURE OF THE ACTION

Dr. Anthony Cerami, Ph.D., is one of the world's foremost biochemists. In 1981, while in charge of a laboratory at Rockefeller University, he made important discoveries which ultimately led to the issuance of various patents, including two United States patents which will not expire until 2018 and 2019. Two pharmaceutical products with annual sales in the billions, which employ the inventions reflected in Dr. Cerami's patents, have already been introduced commercially on a worldwide basis by non-parties to this action, and other products based on the patents are in development.

In June of 1985, the pending patent applications based on Dr. Cerami's work were licensed by Rockefeller University to Chiron Corporation, which is now part of Defendant Novartis AG, pursuant to a license agreement (the "1985 Chiron License Agreement") (Exhibit A). Chiron also retained Dr. Cerami as a consultant and agreed to pay him a royalty of not less than .5% of sales of products covered by the 1985 Chiron License Agreement. Chiron's agreement with Dr. Cerami is confirmed in a writing from Chiron's President dated August 16, 1985 (the "August 1985 Agreement") (Exhibit B). Novartis has acknowledged that the two multi-billion dollar products mentioned above are covered by the 1985 Chiron License Agreement. Dr. Cerami performed services for Chiron for many years and his activities led directly to the receipt by defendants of enormous benefits. Additional millions of dollars are expected to be received by Novartis as a result of the 1985 Chiron License Agreement and the August 1985 Agreement. After Dr. Cerami completed all activities requested of him, and notwithstanding the enormous sums realized and to be realized, Novartis refused to honor the obligation to pay Dr. Cerami under their agreement. This is a suit for money damages based on the defendants' failure to honor that written obligation and the defendants' unjust enrichment based on related conduct and events. A declaration is also sought to require payments on further sales of products covered by the August 1985 Agreement.

ALLEGATIONS COMMON TO ALL CLAIMS FOR RELIEF

THE PARTIES

1. Plaintiff Anthony Cerami, ("Plaintiff" or "Dr. Cerami"), a biochemist, is an individual residing in and a citizen of the State of New York. He is world renowned in his field with hundreds of patents and scientific publications and a member of the National Academy of Science.

2. Defendant Novartis AG ("Novartis") is a corporation organized and existing under the laws of Switzerland, with its principal place of business in Basel, Switzerland. Novartis is the parent company of Novartis Vaccines and Diagnostics, Inc. and both are engaged in the business of the manufacture and sales of pharmaceuticals and other products. Novartis has offices throughout the United States and the world.

3. Defendant Novartis Vaccines and Diagnostics, Inc. ("Chiron"; collectively with Novartis, the "Defendants"), was formerly known as Chiron Corporation up to the time of its acquisition by Defendant Novartis in 2006, when its name was changed. Chiron is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Emeryville, California. Chiron is now a subsidiary of Novartis engaged in the business of the development, manufacture and sales of pharmaceuticals and other products.

JURISDICTION AND VENUE

4. The amount in controversy exceeds the sum of \$75,000, exclusive of interest and costs.

5. Jurisdiction is proper under 28 U.S.C. § 1332 based on diversity of citizenship.

6. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391 and the defendants are subject to jurisdiction in this District in that each defendant named herein is found, transacts business, has an agent or maintains an office within this district, the claims arose all or in part in this district, and the defendants directly or indirectly performed acts within this judicial district.

Dr. Cerami Works on Behalf of Rockefeller and Chiron on the Research, Development and Patenting of Inventions Based on His Discoveries

7. In the late 1970's Dr. Cerami was responsible for directing the research activities of the Laboratory of Medical Biochemistry at the prestigious The Rockefeller University

("Rockefeller"). Under his direction, the laboratory undertook cutting edge research to explore a phenomenon Dr. Cerami had observed while working in Africa on various medical research and treatment projects. He had there observed a reaction to various infections which resulted in the production by the mammalian body of a substance aimed at eradicating the invading element, but which ultimately caused adverse effects which were equal to or greater than the original infection. After some years of work, his laboratory had identified a substance which was originally labeled "cachectin," and later came to be widely known as "TNF" (Tumor Necrosis Factor). This research established the harmful properties of the substance, as well as the remedial benefits of an antibody which could help the body neutralize the adverse effects of TNF. By 1981, these inventions had resulted in the first of a series of patent applications and amendments under the name of Dr. Cerami and a colleague in his laboratory at Rockefeller. At that point, neither the specific identity of TNF, nor the details of the antibodies which neutralize its effects, were identified with the specificity that later emerged.

8. As is typically the case, the rights to all inventions developed in Rockefeller Laboratories belonged to Rockefeller which, in turn, pursuant to its intellectual property policy, was obligated to share certain revenues from these inventions with the actual inventors. Dr. Cerami operated under this policy. The patent applications noted above, and those which followed, became the property of Rockefeller and Dr. Cerami was entitled to share in the revenues received by Rockefeller which derived from his work.

9. On September 8, 1981 an application for a patent was filed in the name of Dr. Cerami and Dr. Masanobu Kawakami, a colleague in Dr. Cerami's laboratory. Application No. 06/299,932 ("the 932 application"). On February 22, 1982 the '932 application was succeeded by a continuation in part. Application No. 06/351,290 ("the '290 application"). On September

7, 1982, another continuation-in-part application was filed. Application No. 06/414,098 (“the ‘098 application”). As noted, Dr. Cerami and Dr. Kawakami assigned all of these patent applications to Rockefeller.

10. In general terms, these patent applications and related publications disclosed the discovery by Dr. Cerami and his colleagues of the existence and source of the substance which came to be known as TNF and the utility of an antibody to neutralize its severe harmful effects (the so-called anti-TNF antibodies). As recently described by Judge Ward of the United States District Court for the Eastern District of Texas (“Ward Opinion”) referring to patents which derived from the ‘098 application, “The patents-in-suits teach that antibodies that neutralize the effects of the mediator [cachectin or TNF] can be used in pharmaceutical compositions and administered to patients to treat disease.”

11. By 1985, it was apparent that Dr. Cerami’s discoveries, as embodied in the then still pending patent applications, had significant commercial possibilities. At that time, Chiron investigated the status of the research headed by Dr. Cerami and the prospects of its commercial application and concluded that Dr. Cerami’s inventions could give rise to significant and valuable opportunities for Chiron. Pursuant to the June 28, 1985 Chiron License Agreement (Exhibit A), Rockefeller granted Chiron an exclusive license to the pending patent applications based on Dr. Cerami’s work, together with all divisions, continuations, continuations-in-part, reissues, renewals, foreign counterparts, extensions or additions thereof, and the related technology inventions and products, including all patents derived from the foregoing. Chiron then assumed control of the program for the development of commercially viable products useable in a variety of medical treatments and indications.

12. By this time other scientists had begun research on the phenomenon and potential applications reflected in Dr. Cerami's work. Papers by others on these subjects were published in scientific journals. Research and testing were undertaken by scientists in various academic laboratories, hospitals and business settings. Dr. Cerami remained the initial inventor and patentee, and his involvement in projects was a great benefit to anyone trying to exploit the inventions reflected in his patents.

13. As Chiron negotiated with Rockefeller over the terms which resulted in the 1985 Chiron License Agreement, its senior executive officers undertook to secure Dr. Cerami's direct involvement on behalf of Chiron. Prior to signing the June agreement, the President of Chiron wrote a letter to Dr. Cerami stating that they viewed his work to reflect an "exciting discovery" with the prospect of "financial rewards" to him "directly from Chiron."

14. During the early part of 1985 and even before the 1985 Chiron License Agreement was signed, Chiron sought to confirm that, if they completed a deal with Rockefeller, Dr. Cerami would work directly with Chiron on the project. Chiron undertook separate negotiations to secure the services of Dr. Cerami in the ongoing research, development and ancillary activities based on the discoveries in the pending patent applications, above and beyond Dr. Cerami's work through Rockefeller. Edward Penhoet, the President of Chiron, and William Rutter, its Chairman and Chief Scientific Officer, specifically and repeatedly represented to Dr. Cerami that his personal commitment and expertise were essential to, and would add great value to the project.

15. Shortly after the 1985 Chiron License agreement was executed, Dr. Cerami entered into an agreement with Chiron whereby plaintiff agreed to serve Chiron in his "individual capacity." This agreement was reflected in a letter prepared by Penhoet or others at

Chiron and signed by Penhoet as President of Chiron, in which Chiron agreed to provide Dr. Cerami with a nominal consulting fee, stock options, and which letter was “also to confirm” that Chiron would pay a royalty of not less than one half of one percent of “net sales on any products on which Chiron pays a royalty to Rockefeller University pursuant to the License Agreement, dated June 28, 1985, between Chiron and Rockefeller.” That letter is dated August 16, 1985. See Exhibit B.

16. In accordance with the parties’ agreement, and in reliance upon the commitment of Chiron to pay a royalty to Dr. Cerami, over the following years up to and including 2006, Dr. Cerami provided valuable services to Chiron, including, but not limited to, the following:

- a. Dr. Cerami continued to perform research and consulting activities with his research team in New York in furtherance of the development activities for Chiron;
- b. Dr. Cerami made many trips to California to the Chiron research facilities and coordinated his activities and those of people he supervised with Chiron research personnel;
- c. Dr. Cerami and his colleagues continued to be the prime movers in the refinement of the patents based on the 1981 applications licensed to Chiron by Rockefeller in 1985, and Dr. Cerami himself was the key scientist involved in the work with the patent attorneys in the United States and in foreign jurisdictions which led to the issuance in 2001 and 2002 patents of the valuable patents upon which Chiron relied to sue for multimillion dollar recoveries;
- d. In subsequent patent litigation and arbitration proceedings based on the patents covered by the Chiron License Agreement, Novartis/Chiron and Rockefeller presented Dr. Cerami as their key witness on critical issues relating to the creation, scope and validity of the patents. Dr. Cerami spent months working with Chiron and Rockefeller counsel in

preparation for the hearings, and was the only claimant representative (other than counsel) present during the entirety of the proceeding.

17. Over the two decades following the August 1985 Agreement, Dr. Cerami and others discovered more about the properties of TNF and the benefits of the antibodies, though the basic inventions reflected in the 1981 applications remained the key to the valuable patents. After nearly twenty years of examination before the United States Patent and Trademark Office, the 1981 patent application ultimately yielded two key patents – U.S. Patents No. 6,309,640 (“the ‘640 Patent”) and 6,419,927 (“the ‘927 Patent”) – which were issued in 2001 and 2002 and will not expire until 2018 and 2019 respectively. Dr. Cerami and his colleague were again listed as inventors on the ‘640 and ‘927 patents, both of which were “assigned” to Rockefeller and licensed by Rockefeller to Chiron under the Chiron License Agreement.

18. Defendants continued to utilize Dr. Cerami’s services through early 2007, when the results of the patent arbitration were announced.

Chiron Fails to Develop and Market a Commercially Viable Product but Benefits from the Exclusive License from Rockefeller by Initiating Patent Litigation

19. Chiron did not develop or make any commercial sales of a product based on the patents. In contrast, other companies have been successful in the development and commercialization of pharmaceutical products based upon the anti-TNF antibodies discovered by Dr. Cerami and which are the subject of the Cerami patents. These products have enjoyed annual sales of several billion dollars and their uses and medical indications have been expanding.

a. Centocor, a subsidiary of drug giant Johnson & Johnson, made a high risk investment in the development of a commercial product based on Dr. Cerami’s work, and its “REMICADE” product was approved by the FDA and is now sold as an antibody to TNF;

b. Abbott Laboratories also risked the expenditure of many millions of dollars and years of work in order to produce a product which survived the clinical tests on human beings and FDA scrutiny. In December 2002, its "HUMIRA " product was approved by the FDA and it is now sold as an antibody to TNF; and

c. In 2006, sales of REMICADE and HUMIRA have exceeded \$3.5 Billion (\$3,500,000,000) and are projected to increase significantly over the next several years.

20. Upon information and belief, other companies have undertaken research and development efforts on antibodies to TNF which may result in the introduction of other commercial products based on Dr. Cerami's work which may also infringe on the subject patents.

21. Having avoided the costly and high risk route of developing, testing and competing for commercial sales of a pharmaceutical product, Chiron instead sought to benefit from its exclusive license with Rockefeller by the initiation of patent litigation against Centocor and Abbott Laboratories.

22. In a lawsuit filed in 2004 in the United States District Court for the Eastern District of Texas, Marshall Division, styled "The Rockefeller University and Chiron Corporation v. Centocor, Inc. and Abbott Laboratories, Civ. Action No. 2:04-cv 168 (TJV)," civil patent infringement was charged against both Centocor and Abbott based on the 2001 and 2002 patents licensed to Chiron under the Chiron License Agreement. Chiron's complaint specifically identified HUMIRA and REMICADE as the offending products.

23. District Judge Ward held a "Markman" hearing to interpret the scope and meaning of the claims asserted in the patents. In the above mentioned opinion dated October 3, 2005, Judge Ward made clear that the 2001 and 2002 patents are directly connected to the patent

applications filed in 1981 and reflect Dr. Cerami's additional work and clarifications subsequent to the initial filing.

24. After Judge Ward issued his October 3, 2005 opinion, Centocor entered into a settlement with Chiron and Rockefeller in December 2005 pursuant to which Centocor received a license under the Cerami patents from Chiron. The amount paid and to be paid to Novartis is substantial and covered by confidentiality agreements.

25. Following the Centocor settlement, the federal court litigation continued with Abbott as the sole remaining defendant. On the eve of a jury trial, the parties reached a settlement which provided for the end of the federal court litigation and for damage claims against Abbott to be arbitrated. The arbitration commenced in late 2006 and continued for approximately 3 weeks. Dr. Cerami worked extensively with counsel for Chiron in preparation for the arbitration, as he had in connection with the earlier litigation. He attended all of the hearings and provided key scientific advice to the lawyers. He was the sole witness offered by Chiron, other than outside experts with no involvement in the relevant events. He testified for many days on direct and cross examination.

26. The result of the arbitration was announced in early 2007. The arbitrators, in large part based on the testimony by Dr. Cerami, awarded plaintiffs the maximum allowable under the arbitration agreement.

27. The terms of the dispositions of the proceedings are the subject of confidentiality agreements. Public information discloses that Abbott and Centocor have sold billions of dollars of products which were the subject of the patent suits. Chiron has received and will continue to receive enormous sums from the patents-in-suit but has failed and refused to pay anything to Dr. Cerami under the August 1985 Agreement.

28. Chiron has paid a royalty to Rockefeller out of its receipts from Abbott and Centocor and continues to share those revenues with Rockefeller. Chiron has thereby confirmed that the amounts it received are covered by its June 1985 Agreement, and are "products on which Chiron pays a royalty to Rockefeller" as those terms are used in the letter it drafted and sent to Dr. Cerami.

29. Dr. Cerami has received and will receive amounts from Rockefeller based on payments Rockefeller has received from Chiron, however, he has not received any part of the royalty promised by Chiron in the August 1985 Agreement.

VIOLATIONS ALLEGED

FIRST CLAIM FOR RELIEF

(Breach of Contract)

30. Defendants have breached the August 1985 Agreement with Dr. Cerami by failing to provide the royalty specified therein of not less than one-half percent (.5%) of net sales of HUMIRA and REMICADE on which Chiron pays (and has paid) a royalty to Rockefeller University pursuant to the License Agreement, dated June 28, 1985, between Chiron and Rockefeller.

31. All conditions precedent have been performed or have occurred. Plaintiff has fulfilled all obligations to Chiron.

32. By reason of Defendants' breach, Plaintiff has been damaged in an amount not less than .5% of net sales of HUMIRA and REMICADE. In 2006, such sales exceeded \$3.5 Billion (\$3,500,000,000).

SECOND CLAIM FOR RELIEF IN THE ALTERNATIVE

(Unjust Enrichment)

33. Plaintiff restates and realleges all of the allegations of paragraphs 1-32 hereof.

34. Since 1985, Dr. Cerami has provided valuable services to Chiron and Novartis, including the following:

a. Dr. Cerami continued to perform research and consulting activities with his research team in New York in furtherance of the development activities for Chiron;

b. Dr. Cerami made many trips to California to the Chiron research facilities and coordinated his activities and those of people he supervised with Chiron research personnel;

c. Dr. Cerami and his colleagues continued to be the prime movers in the refinement of the patents based on the 1981 applications licensed to Chiron by Rockefeller in 1985, and Dr. Cerami himself was the key scientist involved in the work with the patent attorneys in the United States and in foreign jurisdictions which led to the issuance in 2001 and 2002 patents of the valuable patents upon which Chiron relied to secure multimillion dollar payments;

d. In patent litigation and arbitration proceedings based on the patents covered by the Chiron License Agreement, which have already led to the receipt by Novartis of enormous sums and will yield much more, Novartis/Chiron and Rockefeller presented Dr. Cerami as their key witness on critical issues relating to the creation, scope and validity of the patents. Dr. Cerami spent months working with Chiron and Rockefeller counsel in preparation for the hearings, and was the only claimant representative (other than counsel) present during the entirety of the proceeding.

35. At various times after 1985, Chiron knew that Dr. Cerami was acting in furtherance of and reliance upon commitments made to him by Chiron pursuant to the August 1985 Agreement. In particular, during the 2006 arbitration which involved considerable expenditures of time by Dr. Cerami, Chiron reviewed the August 1985 Agreement and continued

to call upon Dr. Cerami's assistance in the litigation and arbitration. At no time during the performance of his services or prior to the completion of the arbitration did Chiron/Novartis state that it would refuse to honor its obligations to Dr. Cerami under the August 1985 Agreement.

36. Following the conclusion of the arbitration Novartis has failed and refused to pay Dr. Cerami at least one half of one percent (.5%) of the sales of products on which it has paid a royalty to Rockefeller.

37. Following the conclusion of the arbitration Novartis has refused to acknowledge the existence of a binding contract with Dr. Cerami covering his services to Chiron. Novartis has thereby brought into issue the existence of a contract and made its unjust enrichment a proper ground for an alternative claim.

38. Novartis has received and continues to receive enormous sums from Abbott and Centocor and may receive additional recoveries from others. Based on proceedings already concluded, Chiron is expected to receive an enormous amount of money, net of all expenses and third-party payments, from Dr. Cerami's patents.

39. Defendants have been unjustly enriched by receiving the benefit of Dr. Cerami's services for which he has not been paid as promised by Chiron.

40. In the event Dr. Cerami does not recover on his claim for breach of contract he is entitled to recover by virtue of Novartis having been unjustly enriched.

41. By reason of the conduct of Defendants, Plaintiff has suffered and continues to suffer damages in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF

(Declaratory Relief)

42. Plaintiff restates and realleges all of the allegations of paragraphs 1-41 hereof.

43. Chiron and Novartis fail and refuse to acknowledge their obligation to provide the royalty specified in the Consulting Agreement of not less than one-half percent (.5%) of net sales of HUMIRA and REMICADE or other products on which Chiron pays, has paid, or will pay a royalty to Rockefeller University pursuant to the License Agreement, dated June 28, 1985, between Chiron and Rockefeller.

44. In addition to HUMIRA and REMICADE it is anticipated that there will be other products covered by the Cerami patents.

45. All conditions precedent have been performed or have occurred. Plaintiff has fulfilled his obligations under the Consulting Agreement. Defendants have failed and refused to pay or acknowledge their obligation to pay a royalty on sales of HUMIRA, REMICADE or other products which it pays a royalty to Rockefeller.

46. Plaintiff will continue to suffer further damages until Chiron and Novartis acknowledge their obligation to pay the royalty specified in the consulting agreement.

WHEREFORE, Plaintiff demands judgment against Defendants:

- a. Awarding Plaintiff damages to be proven at trial in an amount not less than one-half percent (.5%) of past and current net sales of HUMIRA and REMICADE;
- b. Declaring that Plaintiff is entitled to an amount not less than one-half (.5%) of the net future sales of HUMIRA and REMICADE and any other product hereafter sold on which Chiron pays a royalty to Rockefeller University pursuant to the License Agreement, dated June 28, 1985, between Chiron and Rockefeller; and

- c. Awarding the costs of this action and such other and further relief as is just and proper.

Dated: New York, New York
June 13, 2007

TROUTMAN SANDERS LLP

By: _____
Barry J. Brett

The Chrysler Building
405 Lexington Avenue
New York, New York 10174
(212) 704-6200

Attorneys for Plaintiff

EXHIBIT “A”

COPY

AGREEMENT

AGREEMENT made as of the 28th day of June, 1985, by and between CHIRON CORPORATION ("CHIRON"), a California corporation having a principal place of business at 4560 Horton Street, Emeryville, California 94608 and THE ROCKEFELLER UNIVERSITY, an education corporation chartered by the Board of Regents of the State of New York, having an office at 1230 York Avenue, New York, New York ("ROCKEFELLER").

WITNESSETH:

WHEREAS, ROCKEFELLER wishes to conduct a program of research on substances produced in macrophages or monocytes induced by endotoxin (hereinafter referred to as "Cachectins") and is willing to grant a license for a fair and reasonable remuneration to the sponsor of this research under patents covering inventions arising from and relating to this research; and

WHEREAS, ROCKEFELLER and CHIRON wish to cooperate in further investigating Cachectins, and in the demonstration of clinical utility of products related to Cachectin; and

WHEREAS, CHIRON wishes to be the sponsor of this research and obtain exclusive license rights to manufacture and sale of related inventions;

NOW, THEREFORE, in consideration of the mutual benefits to be derived hereunder, the parties hereto agree as follows:

1. DEFINITIONS

1.1 "PARTY" shall mean either CHIRON or ROCKEFELLER and "PARTIES" shall mean both CHIRON and ROCKEFELLER.

1.2 "LICENSED PATENT RIGHTS" shall mean: a) all patent applications which are listed in Exhibit A annexed hereto and all patents which may issue thereon; b) such PROJECT PATENT APPLICATIONS or PROJECT PATENTS as to which CHIRON shall exercise the right of first refusal provided for in Paragraph 2.5 of this Agreement; and c) all patent applications which are divisions, continuations, continuations-in-part, reissues, renewals, foreign counterparts, extensions or additions of or to such patent applications or patents and all patents which may issue thereon.

1.3 "PROJECT INVENTION(s)" shall mean the inventions wholly or partially made by ROCKEFELLER in the course and as a result of the CACHECTIN RESEARCH PROJECT.

1.4 "TECHNICAL INFORMATION" shall mean any and all technical data, information, materials and other know-how controlled by ROCKEFELLER, in a tangible form, arising from the Research Project, which is needed in the practice of the LICENSED PATENT RIGHTS.

1.5 "PROJECT PATENT APPLICATION(s)" and "PROJECT PATENT(s)" shall mean any patent application(s) or patent(s) claiming any invention embodied in the PROJECT INVENTION(s) or

employed in its use and any reissue, division, continuation, or continuations-in-part thereof, for which CHIRON pays the costs of filing, prosecuting, and maintenance.

1.6 "CACHECTIN RESEARCH PROJECT" shall mean the program of research on Cachectins which has been and is being conducted by Dr. Anthony Cerami and his colleagues at ROCKEFELLER which is described in Exhibit B attached hereto.

1.7 "TERRITORY" shall mean all countries of the world.

1.8 "GOODS" shall mean any and all products which embody or the manufacture or use of which employ TECHNICAL INFORMATION or LICENSED PATENT RIGHTS.

1.9 "NET SALE PRICE" shall mean the total price of GOODS which are sold, leased, or otherwise disposed of, for any purpose, less normal deductions which reduce the amount actually received by CHIRON, such as sales taxes, agency commissions, refunds, rebates, allowances for return of goods for defective quality, and freight or cash discounts.

In the case of GOODS containing additionally one or more biologically-active components other than Cachectins ("Combination GOODS"), the Net Sales Price will be calculated by multiplying the Net Sales Price of the Combination GOODS by the fraction $A/A+B$, where A is the direct cost of purchasing or manufacturing of the GOODS in one dosage unit of the Combination Product and B is the direct cost of purchasing or manufacturing all the other biologically-active components in one dosage unit of the Combination GOODS.

2. RESEARCH PROJECT

2.1 ROCKEFELLER will conduct the research described in its proposal entitled "CACHECTIN RESEARCH PROJECT," attached as Exhibit B.

2.2 CHIRON will provide funding to ROCKEFELLER for one (1) year for the RESEARCH PROJECT in accordance with the budget for the RESEARCH PROJECT attached as Exhibit C (hereinafter "Budget"). Payments pursuant to this funding commitment shall be made quarterly in advance on the first day of each calendar quarter and continuing during the one year period of research support provided in the Budget. ROCKEFELLER shall provide detailed statements showing the estimated research costs to be incurred during each quarter. ROCKEFELLER's investigators will have full flexibility in the expenditure of the budgeted funds within the context of the agreed upon CACHECTIN RESEARCH PROJECT.

2.3 Dr. Anthony Cerami will be the Principal Investigator of the CACHECTIN RESEARCH PROJECT at ROCKEFELLER and shall have full control over the direction of the CACHECTIN RESEARCH PROJECT at ROCKEFELLER. Dr. Pablo Valenzuela will be responsible for Cachectin research at CHIRON. It is anticipated that there will be close collaboration between the ROCKEFELLER and CHIRON personnel in order to coordinate research efforts.

2.4 Dr. Cerami or another Research Project Investigator designated by Dr. Cerami will supply CHIRON with a reasonably detailed written report on the status of the CACHECTIN RESEARCH PROJECT at reasonable intervals, but at least quarterly.

2.5 ROCKEFELLER agrees that any PROJECT INVENTION(s) in the CACHECTIN RESEARCH PROJECT whether patentable or not, made during the term of the RESEARCH PROJECT by ROCKEFELLER faculty members, employees, agents, or others who are under ROCKEFELLER's control and who are working on the RESEARCH PROJECT shall be promptly disclosed by ROCKEFELLER to CHIRON and CHIRON shall have the right of first refusal to obtain an exclusive license, with the right to grant sublicenses, to make, have made, use, and sell products incorporating such PROJECT INVENTION(s). Said right of first refusal may be exercised at any time during a period of ninety (90) days after submission to CHIRON of such PROJECT INVENTION(s), by notice in writing advising that CHIRON wishes to proceed with patent prosecution at CHIRON's expense. The license grant shall be pursuant to the terms and conditions provided in Section 4 hereof. In the event that CHIRON does not exercise such right within the period specified, ROCKEFELLER shall be free to license third parties.

2.6 ROCKEFELLER and CHIRON recognize the traditional freedom of all scientists to publish and present promptly the results of their research. ROCKEFELLER and CHIRON also recognize that exclusive patent rights can be jeopardized by public disclosure prior to the filing of suitable patent applications. Therefore, ROCKEFELLER will assure that each proposed publication, before submission to a publisher, will be submitted to CHIRON for review in connection with preservation of exclusive patent rights. CHIRON shall have thirty (30) days in which to review the publication, which shall be extended up to an additional

sixty (60) days when CHIRON states substantial and reasonable need for such extension. By mutual agreement, this period may be extended as necessary to protect patent rights or other substantial interests. In cases where no information is relevant to any projected patent claim, CHIRON will allow for simultaneous submission of the publication to the publisher and CHIRON where appropriate.

3. PATENTS

3.1 ROCKEFELLER shall retain title to all PROJECT INVENTION(s) made solely by ROCKEFELLER faculty members, employees, agents or others who are under ROCKEFELLER's control.

3.2 All PROJECT INVENTION(s) jointly made by ROCKEFELLER faculty members, employees, agents or others who are under ROCKEFELLER's control and CHIRON employees, consultants or others who are under CHIRON's control shall be equally owned by ROCKEFELLER and CHIRON.

3.3 CHIRON shall retain title to all inventions relating to Cachectins made solely by CHIRON employees, consultants or others who are under CHIRON's control.

3.4 CHIRON shall promptly decide whether or not; i) CHIRON desires ROCKEFELLER to file U.S. and/or foreign PROJECT PATENT APPLICATION(s) on any PROJECT INVENTION(s) or portion thereof which may be patentable which result from research conducted solely by ROCKEFELLER or, ii) CHIRON intends to file U.S. and/or foreign PROJECT PATENT APPLICATION(s) on any PROJECT

INVENTION(s) or portion which may be patentable which results from research conducted jointly by ROCKEFELLER and CHIRON. Independent patent counsel agreeable to both Parties shall be selected to file and prosecute any such PROJECT PATENT APPLICATION(s), including divisions, continuations, continuations-in-part, and reissues. Representatives of both parties shall be able to meet or consult with patent counsel at reasonable times and places.

3.5 The costs of patent counsel's evaluation of any PROJECT INVENTION(s), and of the preparation, filing, prosecuting, and maintaining PROJECT PATENT APPLICATION(s) and PROJECT PATENT(s) which CHIRON wishes to have filed shall be borne by CHIRON.

3.6 Patent counsel shall deliver to ROCKEFELLER and CHIRON any patentability search reports made by patent counsel including any patents located, a copy of each PROJECT PATENT APPLICATION(s) which covers a PROJECT INVENTION(s), and a copy of each PROJECT PATENT(s) that issues thereon.

3.7 CHIRON shall promptly advise ROCKEFELLER of any decision not to file a PROJECT PATENT APPLICATION(s), not to continue prosecution, or not to maintain a PROJECT PATENT(s) in adequate time to allow ROCKEFELLER, at its own cost, to effectuate such filing, prosecution, or maintenance if it so desires. Nothing herein is intended or shall be construed as obligating ROCKEFELLER to apply for any U.S. or foreign patent at its own expense, or to defend, enforce, or support any PROJECT PATENT(s) or PROJECT PATENT APPLICATION(s) which may be issued.

4. LICENSE

4.1 ROCKEFELLER hereby grants and CHIRON hereby accepts a sole and exclusive license, including the right to grant sublicenses under terms consistent with this Agreement, under TECHNICAL INFORMATION and LICENSED PATENT RIGHTS, and for the lives of such patents, to make, have made, use, and sell products embodying the inventions thereof in any country of the TERRITORY, except to the extent that ROCKEFELLER's right to do so may be limited under the provisions of any of the following:

- (a) 35 United States Code Chapter 38, Section 201 et. seq. and regulations promulgated thereunder,
- (b) other applicable law or regulation, or
- (c) ROCKEFELLER's Institutional Patent Agreement with the United States Department of Health and Human Services, as amended, dated June 15, 1973,

none of which foregoing cited matters prevents the grant of the license herein described. Provided only that ROCKEFELLER is satisfied that the licensee is making a substantial and good faith effort to achieve practical application of the subject invention and its public use, ROCKEFELLER agrees to use reasonable and proper efforts to extend exclusivity of the license consistent with the aforesaid U.S. government rights and policies should U.S. government action limit such exclusivity.

4.2 In the event that no PROJECT PATENT issues in a particular country of the TERRITORY, CHIRON's license in that country shall become irrevocable and fully paid eight (8) years from the date of the first commercial sale of GOODS in that country.

4.3 In consideration of the exclusive license grant of Paragraph 4.1, CHIRON shall pay or cause to be paid to ROCKEFELLER a one-time payment of the sum of fifty thousand dollars U.S. (\$50,000.00) within thirty (30) days from the filing of the first NDA with the United States Food and Drug Administration on a formulation involving LICENSED PATENT RIGHTS. Such payment shall be credited against royalties due under Paragraph 4.4 of this Agreement, whenever such royalties may become due.

4.4 In consideration of the rights and any licenses granted hereunder, CHIRON shall pay or cause to be paid to ROCKEFELLER the following amounts:

(1) For GOODS sold, leased, or otherwise disposed of by CHIRON worldwide where i) such sales would, but for the grant of license pursuant to Paragraph 4.1 under patents solely owned by ROCKEFELLER or the exercise of rights under patents owned equally by ROCKEFELLER and CHIRON, infringe a valid claim of one or more issued, unexpired patents included in LICENSED PATENT RIGHTS and ii) the sale of any similar product by a third party would infringe a valid claim of one or more such patents, royalties equal to:

- (a) ~~Seven and one half per cent (7.5%)~~ of the NET SALES price of cumulative sales, up to two hundred thousand United States Dollars (\$200,000.00 U.S.);
- (b) Six and three quarters per cent (6.75%) of the NET SALES price of the next three hundred thousand United States Dollars (\$300,000.00 U.S.) of cumulative sales;
- (c) Six per cent (6%) of the NET SALES price of the next five hundred thousand United States Dollars (\$500,000.00 U.S.) of cumulative sales;
- (d) Five per cent (5%) of the NET SALES price of any cumulative sales thereafter.

(2) For all other sales in all countries of GOODS by CHIRON worldwide, the applicable royalty rates shall be fifty per cent (50%) of the rates shown in (1)(a) through (1)(d) above. In the event, no patent protection is obtained for the PROJECT INVENTION(s) or TECHNICAL INFORMATION, the parties will, in good faith, negotiate new, lower royalty rates.

(3) For all sublicenses granted by CHIRON under the TECHNICAL INFORMATION and LICENSED PATENT RIGHTS, a royalty rate of fifteen percent (15%) of all gross receipts received by CHIRON from such sublicensees.

The obligation to pay royalties hereunder is imposed only with respect to the sale of GOODS regardless of the number

of valid claims which cover such GOODS. Upon expiration of all applicable patents included in LICENSED PATENT RIGHTS in a particular country of the TERRITORY, CHIRON's license in such country shall become irrevocable and fully paid.

4.5 The PARTIES agree that if CHIRON can show to the reasonable satisfaction of ROCKEFELLER that the royalty rates herein set forth do not permit CHIRON an equitable profit, the PARTIES will undertake good faith efforts to negotiate new royalty rates which will permit an equitable return to both PARTIES.

4.6 Within 60 days of the date of this Agreement, CHIRON shall reimburse ROCKEFELLER for all amounts expended prior to the date of this Agreement on the prosecution of the patent applications and patents included in LICENSED PATENT RIGHTS, and shall continue to reimburse ROCKEFELLER for such additional filing and prosecution costs as shall be incurred by mutual consent during the term of this Agreement.

4.7 CHIRON shall have the right to sublicense third parties to practice TECHNICAL INFORMATION and LICENSED PATENT RIGHTS, subject to ROCKEFELLER's approval of the sublicensee.

4.8 ROCKEFELLER agrees to use reasonable efforts, short of litigation, to resist any claim which might effect the exclusive nature of any license granted hereunder. However, should it develop at any time during the term of this Agreement that the license granted herein is rendered non-exclusive in any country of the TERRITORY as a result of any governmental or other action, then the royalty due to ROCKEFELLER from CHIRON on the

affected product in that country shall be reduced by fifty percent (50%), but in no event shall the royalty rate of CHIRON be less favorable than the royalty rate of any other licensee in that country.

4.9 Upon commencement of commercial sales of any GOODS which generate a royalty to ROCKEFELLER pursuant to this Agreement, CHIRON shall, within sixty (60) days of the close of the calendar quarter, make quarterly reports to ROCKEFELLER showing the total net sales of GOODS and the calculation of royalties thereon. Any royalty then due and payable shall be included with such report. CHIRON's records shall be open to inspection by ROCKEFELLER or a certified public accountant designated by ROCKEFELLER, at reasonable times, for the sole purpose of verifying the accuracy of the reports and royalty payments.

4.10 CHIRON shall have the right to institute patent infringement proceedings against third parties based on any LICENSED PATENT RIGHTS described in Paragraph 1.2 hereof. If CHIRON does not institute infringement proceedings against such third parties, ROCKEFELLER shall have the right to institute such proceedings. The expenses of such proceedings, including lawyers' fees, shall be borne by the PARTY instituting suit. Each PARTY shall execute all necessary and proper documents and take all other appropriate action to allow the other PARTY to institute and prosecute such proceedings. Any award paid by third parties as a result of such proceedings (whether by way of settlement or otherwise) shall first be applied toward reimbursement for the legal fees and expenses incurred, ~~and~~ the excess, if

any, shall be divided equally between the PARTIES. So long as such infringement proceedings continue, CHIRON shall be permitted to reserve any royalty due to ROCKEFELLER on sales of the affected product in the country in question until such time as the proceedings have been concluded. If the LICENSED PATENT is finally held to be valid and infringed by any such third party, the reserved royalty shall thereupon be promptly paid to ROCKEFELLER; if such LICENSED PATENT is finally held to be unenforceable or invalid, then ROCKEFELLER shall not be entitled to the reserved royalty and no further royalty shall be due by CHIRON or its sublicensee under that LICENSED PATENT; royalties theretofore paid may be retained, however.

4.11 The terms of this Agreement shall be equally applicable to each country of the TERRITORY and CHIRON shall be obligated to pay royalty as provided hereinabove wherever it practices TECHNICAL INFORMATION and/or LICENSED PATENT RIGHTS.

4.12 At the request of ROCKEFELLER no more frequently than twice each year, CHIRON shall make available to ROCKEFELLER a written report on its or its sublicensees' developmental progress with respect to each invention covered by TECHNICAL INFORMATION and/or LICENSED PATENT RIGHTS.

4.13 Should CHIRON decide at any time during the term hereof that it will no longer commercially pursue development of an invention covered by TECHNICAL INFORMATION or LICENSED PATENT RIGHTS, CHIRON shall promptly notify ROCKEFELLER of its decision and upon request from ROCKEFELLER, shall take whatever steps are necessary to assure reversion to ROCKEFELLER of all rights to that invention transferred to CHIRON hereunder.

4.14 If within two (2) years of exercising its licensing rights to a particular invention covered by TECHNICAL INFORMATION or LICENSED PATENT RIGHTS, CHIRON has not taken reasonable steps towards commercialization of that invention, CHIRON upon request from ROCKEFELLER shall take whatever steps are necessary to assure reversion to ROCKEFELLER of all rights to that invention transferred to CHIRON hereunder.

5. CONFIDENTIALITY AND PUBLICITY

5.1 Protection of Confidential Information. Both parties agree to take appropriate measures to protect the confidentiality of any and all information relating to Cachectins disclosed or made available to the other which is treated by the disclosing party as confidential and (i) if in written or other tangible form, is designated in writing as "Confidential," and (ii) if disclosed orally, the information is included in a written summary delivered to the other party within forty (40) days of such oral disclosure (the "Confidential Information"). Each party agrees to use the same degree of care that it employs with respect to its own information which it does not desire to have published or disseminated to protect the Confidential Information. Each party agrees to disclose the Confidential Information solely to those of its employees, the employees of its Affiliates, or government regulatory agencies as are necessary for the purpose of this Agreement. However, neither party shall be obligated to treat information received under this Agreement as Confidential Information if such information:

(a) Was rightfully in the receiving party's possession or was rightfully known by it prior to receipt from the other party; or

(b) Is or becomes public knowledge without the fault of the receiving party; or

(c) Is or becomes rightfully available to the receiving party without confidential restriction from a source not under such party's control; or

(d) Is required to be disclosed without restriction pursuant to an order of a court of competent jurisdiction or is required to be disclosed without restriction by a government agency to satisfy regulatory requirements; provided, however, that the party who is obligated to so disclose the Confidential Information shall give the other party reasonable notice prior to such disclosure and shall use its best efforts to ensure that the court or government agency agrees to maintain the Confidential Information in confidence.

5.2 Continuation of Obligations. The obligations imposed by paragraph 5.1 with respect to the protection of the Confidential Information shall continue during the life of this Agreement and for a period of five years after its termination.

5.3 CHIRON will not use directly or by implication the name of ROCKEFELLER, or the name of any member of the faculty or staff of ROCKEFELLER, without the prior written approval of ROCKEFELLER with the exception if the right to use the name ROCKEFELLER as required by order of a court of competent jurisdiction, a request of any governmental agency or to satisfy regulatory or patent application requirements.

6. PRODUCT LIABILITY

CHIRON agrees to indemnify and hold harmless ROCKEFELLER and its trustees, officers, agents, faculty, employees, and students from any and all liability arising from injury or damage to persons or property resulting directly or indirectly from CHIRON's use, manufacture, or sale of any product covered by TECHNICAL INFORMATION or LICENSED PATENT RIGHTS.

7. NOTICE

Any notice required to be given pursuant to this Agreement shall be made by certified mail, return receipt requested, by one PARTY to the other PARTY.

In the case of CHIRON, notice should be mailed to:

CHIRON CORPORATION

4560 Horton Street

Emeryville, CA 94608

Attn: Office of the President

In the case of ROCKEFELLER, notice should be mailed to:

William H. Griesar, Esq.

Vice President and General Counsel

The Rockefeller University

1230 York Avenue

New York, New York 10021

8. LAW TO GOVERN

This Agreement shall be interpreted and governed in accordance with the laws of the State of New York.

9. ASSIGNMENT

This Agreement may be assigned by CHIRON with the prior written approval of ROCKEFELLER, such approval not to be unreasonably withheld.

10. TERMINATION

10.1 CHIRON shall have the right to terminate this Agreement at any time upon ninety (90) days prior written notice to ROCKEFELLER, provided, however, that termination shall not affect the research support commitment provided for in Paragraph 2.2. hereof. Such termination shall automatically terminate the right of first refusal provided in Paragraph 2.5 and any license herein granted as of the effective date of termination, but shall not relieve CHIRON of the obligation to pay royalties for any period prior to the effective date of termination. In the event of such termination, CHIRON agrees to deliver to ROCKEFELLER all test, clinical, and other technical data developed by CHIRON concerning the affected portion of the TECHNICAL INFORMATION and/or LICENSED PATENT RIGHTS, and ROCKEFELLER shall have the right to use such data in any manner it deems fit, including, but not limited to, the licensing of third parties.

10.2 Either party may terminate this Agreement in the event of a material breach by the other party, provided only that the offending party is given notice of the breach and a reasonable time, not to exceed thirty (30) days, in which to cure such breach.

10.3 Any termination of this Agreement and of the license granted hereunder shall also terminate any sublicense therefore.

11. ENTIRE UNDERSTANDING

This Agreement represents the entire understanding between the PARTIES and supersedes any other agreement expressed or implied by the PARTIES on the RESEARCH PROJECT and/or licensing of related inventions, information, and patents.

12. RELATIONSHIP OF THE PARTIES

Both parties are independent contractors under this Agreement. Nothing contained in this Agreement is intended, or is to be construed so as to constitute CHIRON and ROCKEFELLER as partners or joint venturers, nor is either party the employee or agent of the other nor are the employees or agents of either party employees or agents of the other party. Neither party hereto shall have any express or implied right or authority to assume or create any obligations, on behalf of or in the name of the other party or to bind the other party to any other contract, agreement or undertaking with any third party.

13. FORCE MAJEURE.

Neither ROCKEFELLER nor CHIRON shall be liable for any failure or delay in performance under this Agreement which is due in whole or in part directly or indirectly to any cause of any nature beyond the reasonable control of such party; including, without in any way limiting the generality of the foregoing,

fire, explosion, earthquake, storm, flood, strike, lockout, activities of a combination of workmen or other labor difficulties, war, insurrection, riot, act of God or the public enemy, law, act, order, export control regulations, proclamation, decree, regulation, ordinance, or instructions of Government or other public authorities, or judgment or decree of a court of competent jurisdiction (not arising out of breach by such party of this Agreement). In the event of the happening of such a cause, the party so affected shall give prompt written notice to the other party, stating the period of time the same is expected to continue and shall take all reasonable measures to ensure that the effects of such case of force majeure are kept as minimal as possible.

14. COUNTERPARTS

This Agreement has been executed in two counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the PARTIES have caused this Agreement to be duly executed as of the day and year first above written.

THE ROCKEFELLER UNIVERSITY

CHIRON CORPORATION

BY: 

BY: 

TITLE: Vice President & General Counsel

TITLE: President/CEO

THE ROCKEFELLER UNIVERSITY and
CHIRON CORPORATION

EXHIBIT A

Licensed Patent Rights

<u>Country</u>	<u>Application No.</u>	<u>Filing date</u>
United States	414,098	9/7/82
(This application is a continuation in part of U.S. serial numbers 351,290 filed 2/22/82 and 299,932 filed 9/8/81, now abandoned.)		
Australia	89902/82	9/8/82
Canada	410,994	9/8/82
Japan	57-502997	9/8/82
European Patent Application designating: Austria	82902957.8	4/21/83
Belgium		
Switzerland		
Lichtenstein		
F.R. of Germany		
France		
United Kingdom		
Luxembourg		
Sweden		
The Netherlands		

THE ROCKEFELLER UNIVERSITY
and CHIRON CORPORATION

EXHIBIT B

Research Project

1. Effect of cachectin antagonists on shock. Since cachectin is produced by macrophages under conditions simulating sepsis, an attempt will be made to determine whether this hormone mediates part or all of the shock syndrome that accompanies gram-negative infection. A highly specific antiserum to cachectin will be administered to mice in an attempt to block the effects of subsequent endotoxin administration. In addition, synthetic analogues of cachectin will be used in an attempt to antagonize the effect of the hormone. Other forms of shock, including shock secondary to hemorrhage, malaria, burns, and other insults in experimental animals will be studied as well.

2. Measurement of cachectin production in vivo. Since it is exceedingly difficult to measure cachectin production in vivo using bioassay, radioreceptor assay, or radioimmunoassay techniques, owing to the short plasma half-life of the hormone, we intend to measure production of the hormone in vivo by host mononuclear cells, using the method of northern blot analysis. A synthetic oligonucleotide probe or cloned gene will be used to this end, and production of the hormone by peripheral blood monocytes will be assessed in animals and in humans under a variety of clinical circumstances, in an effort to shed light on the conditions leading to hormone synthesis in nature.

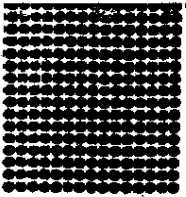
3. Isolation of other macrophage mediators. Crude endotoxin-stimulated macrophage medium contains substance(s), presumably protein in nature, capable of stimulating the hormone sensitive lipase, inhibiting fatty acid synthetase, and inhibiting acetyl coA carboxylase in 3T3-L1 adipocytes.

We intend to isolate these factor(s); and assess their contribution to cachexia in chronically diseased animals.

THE ROCKEFELLER UNIVERSITY and
CHIRON CORPORATIONEXHIBIT CCachectin Research Project Budget

PERSONNEL	EFFORT	SALARY	FRINGE BENEFITS	TOTAL
Research Associate	100%	\$ 23,000	\$ 5,750	\$ 28,750
Technician	50%	<u>9,650</u>	<u>2,413</u>	<u>12,063</u>
Subtotal		\$ 32,650	8,163	40,813
SUPPLIES				
Chemicals and reagents			2,000	
Columns			2,000	
Glass and Plasticware			1,500	
Tissue Culture Supplies			2,000	
				7,500
TOTAL DIRECT COSTS				48,313
INDIRECT COSTS @ 60% (MTDC)				<u>28,987</u>
GRAND TOTAL				\$ 77,300

EXHIBIT “B”



1500 HORTON STREET
EMERYVILLE CA 94608
TELEPHONE: (415) 655-8730
TELEX: 176247 CHIRON EMVL

CHIRON
CORPORATION

05634-AKH Document 1 Filed 06/13/2007 Page 43 of 43

August 16, 1985

Dr. Anthony Cerami, Ph.D.
430 E. 63rd Street
New York, NY 10021

Dear Tony:

In accordance with our recent conversations, I am enclosing two originals of the consulting agreement which will cover your work with us in your individual capacity. If the document is acceptable, please sign both copies and return one to me.

In addition, if you join us, and subject to the approval of Chiron's Board of Directors, we will offer you the right to purchase ten thousand shares of Chiron stock under a non-qualified stock option plan for share purchase by consultants and independent contractors.

This letter is also to confirm that Chiron will pay you a royalty of between one-half percent (.5%) and one percent (1.0%) of net sales on any products on which Chiron pays a royalty to Rockefeller University pursuant to the License Agreement, dated June 28, 1985, between Chiron and Rockefeller.

I am much pleased that you are going to be working with us on this project. I look forward to both excellent scientific achievements and the marketing of an outstanding pharmaceutical product.

Sincerely,

Edward E. Penhoet
President

EP/pta